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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,085

04/18/2005

Thierry Massfelder

BJS-3665-133

9193

23117

7590

06/08/2007

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/520,085	Applicant(s) MASSFELDER ET AL.	
	Examiner Anne M. Gussow	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-20, 23-26, 31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 23-26, 31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 21, 22, 27-30, 32, 36, and 37 have been cancelled.  
Claims 17 and 33-35 have been amended.
2. Claims 17-20, 23-26, 31, and 33-35 are pending and under examination.
3. The following Office Action contains NEW GROUNDS of rejections.

### ***Objections Withdrawn***

4. The objections to the specification have been withdrawn in view of applicant's amendments to the specification.

### ***Rejections Withdrawn***

5. The rejection of claims 17-26 and 31-35 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.
6. The rejection of claims 17-26 and 31-35 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

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7. The rejection of claims 17-21, 23-26, and 31-35 under 35 U.S.C. 103(a), as being unpatentable over Ogata, et al. in view of Burton, et al. is withdrawn in view of applicant's arguments and the new ground of rejection.

### ***NEW GROUNDS OF REJECTIONS***

#### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 17 recites the limitation "the tumor" in line 3. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 17-20, 23-26, 31, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata, et al. (EP 1 197 225 A1, as cited in previous office action) in view of Iwamura, et al. (Cancer, 1999. Vol. 86 No. 6, pages 1028-1034) in view of Burton, et al. (Biochemical and Biophysical Research Communications, 1990. Vol. 167, No.3, as cited in previous office action).

The claims recite a method for treating a kidney cancer comprising the administration to a subject of an effective dose of a PTHrP antagonist for inhibiting or decreasing tumor growth, said PTHrP antagonist being an anti-PTHrP antibody, wherein said subject is a human subject, wherein said kidney cancer is selected from the group consisting of consisting of papillary carcinoma (chromophiles), chromophobe cell carcinoma, Bellini carcinoma, clear cell carcinoma, or unclassified renal cell carcinomas, wherein the kidney cancer is a solid malignant tumor, wherein the PTHrP antagonist is a compound binding the PTHrP receptor and inhibiting partially or totally a binding of PTHrP to its receptor, wherein the PTHrP antagonist is a PTHrP competitive receptor antagonist.

Ogata, et al. teach a method for treating hypercalcemia by administering a humanized monoclonal anti-PTHrP antibody to a rat cancer model (page 13, example 4) in which the PTHrP antibody binds to the PTHrP receptor (page 5, paragraph 37). Ogata, et al. do not teach treating kidney cancer. This deficiency is made up for in the teachings of Iwamura, et al. and Burton, et al.

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Iwamura, et al. teach that elevated serum PTHrP has been detected in many renal cell carcinoma patients with hypercalcemia (bottom of page 1028).

Burton, et al. teach PTHrP antiserum specifically inhibited the growth of a human renal cell carcinoma cell line *in vitro* (figure 3, table 1, and page 1137 2<sup>nd</sup> paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have used the anti-PTHrP antibody of Ogata, et al. to treat kidney cancer as taught by Burton, et al. in view of Iwamura, et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have treated kidney cancer with the antibody of Ogata, et al. because Iwamura, et al. teach that PTHrP is elevated in renal cell carcinoma patients. Additionally, Burton, et al. teach that inhibition of PTHrP reduced the growth of renal cancer cells but not ROS 17/2.8 cells (a rat osteoblastic osteocarcinoma cell line which possesses PTH receptors) or bovine adrenal medullary cells (page 1137, 2<sup>nd</sup> paragraph). One of ordinary skill in the art would progress to an animal (in vivo) experimental model of kidney cancer (such as the rat model of Ogata) after attaining a favorable reduction of cell growth in vitro. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have treated kidney cancer in view of Iwamura, et al. and Burton, et al. with the antibody of Ogata, et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the references.

**Conclusion**

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

May 31, 2007



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER